

## REMARKS

Reconsideration and allowance of the application are respectfully requested in light of the foregoing amendments and the following remarks.

Claims 15, 16, 18, 19, 21, 22 and 24 – 29 were pending in the application. Claims 25, 26 and 27 are cancelled herein without prejudice or disclaimer.

Independent claims 15 and 24 have been amended to recite that the claimed vaccine and method, respectively, are administered to developing embryos "having maternal antibodies" to infectious bronchitis virus. Support therefor may be found in original claim 10 as filed on February 2, 2001. Claims 15 and 24 have also been amended to incorporate the efficacy results set forth in Table 13 on page 17 of the application.

Independent claim 19 has been amended to recite the strain of IB virus utilized in the claimed vaccine. Support therefor may be found in the specification on page 5, lines 11-12.

The remaining claims 16, 28 and 29 have been amended to correct minor informalities, and thereby attain consistency with the independent claims from which they depend. All the remaining claims now incorporate the term "comprises" instead of "consisting essentially of".

New claims 30, 31 and 32 are each directed to additional embodiments of the invention. Support for claim 30 is taken from the specification at page 5, line 26 and for claim 31 at page 5, lines 12-13. Support for claim 32 may be found on page 5, lines 11-12.

Entry of the foregoing amendments and new claims is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the amendments set forth above. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claim 28 was objected to under 37 C.F.R. §1.75 as being a substantial duplicate of claim 29. This objection is believed to be rendered moot by the amendment herein to claim 28.

Claims 15, 26, 18 and 24-29 were rejected under 35 U.S.C. §112, first and second paragraphs, with the Office objecting to the recitation of the phrase "consisting essentially of". It is believed that these rejections are now rendered moot in view of the amendments above. Withdrawal of the rejections is therefore respectfully urged.

Claims 15, 16, 18, 19, 21, 22, and 24 -29 stand rejected under 35 U.S.C. §103(a) as being obvious over the cited Wakenell et al. article. This rejection is respectfully traversed in regard to the remaining claims for the following reasons.

Wakenell et al. do not describe a vaccine, or a method of vaccination, which is especially efficacious against developing embryos that have maternal antibodies to IB virus. In this regard, the Office's attention is directed to the attached DECLARATION OF FRANS DAVELAAR, by one of the named inventors in the present application. The Declaration compares the results obtained by the present applicants and summarized in Example 3 of the specification, with those obtained by Wakenell et al. and summarized in TABLES 4 and 5 of that reference. As set forth by Dr. Davelaar, the results in Example 3 were obtained using commercially obtained eggs bearing maternal antibodies to the IB virus (as with Wakenell et al.). The present applicants attained comparable hatch results (~90% vs. 90-92% for Wakenell et al.) However, efficacy for the present Applicants was at least 89%. In contrast, in each of the two experiments from which the results in TABLES 4 and 5 were generated, efficacy against challenge from virulent IB virus ranged from a high of 86% to as low as 50%. The methodology utilized by the present applicants to assess efficacy, namely the CST method, is clearly comparable to the methods utilized by Wakenell et al. In this regard, the Office's attention is further directed to

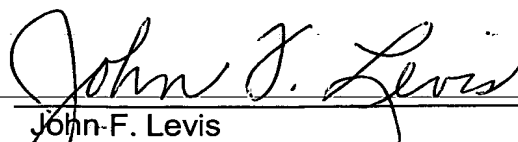
the reference entitled "International Symposium on Infectious Bronchitis" attached as Exhibit 1 to the Declaration. In particular, Tables 1 and 5 in Exhibit 1 show a side-by-side comparison of efficacy results using "clinical signs/symptoms" vs. the "ciliostasis test" (another name for CST).

As the attached Declaration demonstrates, the present inventors defied the conventional thinking by developing a vaccine and method of administration therefor. They clearly attained unexpected results – results which could not have been predicted from the disclosure of Wakenell et al. They obtained an in ovo vaccine which protects post-hatch poultry (having maternal antibodies) from challenge with virulent IB virus. The present applicants should be therefore be entitled to patent protection for their discovery.

Based on the foregoing, it is respectfully submitted that the claimed invention is not obvious in view of Wakenell et al.'s disclosure. Withdrawal of the obviousness rejection is therefore respectfully urged.

The application is believed to be in proper condition for allowance, and prompt, favorable action thereon is earnestly solicited. Should Examiner Foley feel that any other point requires consideration, then she is cordially invited to contact the undersigned.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**AMENDED CLAIMS:**

15. (Four Times Amended) An in ovo vaccine for protecting chickens having maternal antibodies to infectious bronchitis (IB) virus from exposure to virulent [infectious bronchitis] IB virus, wherein said vaccine [consists essentially of] comprises a solution containing, on a chicken egg basis, a live avirulent strain of infectious bronchitis virus in an immunogenically-effective amount within the range of about  $10^{-1.0}$  EID<sub>50</sub> per egg to about  $10^{2.0}$  EID<sub>50</sub> per egg, wherein [said solution is a reconstituted solution of a commercial vaccine against infectious bronchitis which has not been approved or indicated for in ovo administration] said vaccine has a percentage (%) protection in post-hatch member chicks surviving at 3 weeks of age of at least 89% against challenge from virulent IB virus.

16. (Twice Amended) The vaccine of claim 15, wherein the immunogenically-effective amount [is efficacious against subsequent post-hatch exposure of the chicken to virulent infectious bronchitis virus and] does not decrease the percentage of in ovo vaccinated chicken eggs that hatch upon the expiration of the incubation period below 72%.

19. (Twice Amended) A poultry vaccine against infectious bronchitis virus (IBV) comprising a live avirulent strain of infectious bronchitis virus in an immunologically effective amount for in ovo administration of about  $10^{-1.0}$  EID<sub>50</sub> per dose to about  $10^{2.0}$  EID<sub>50</sub> per dose, wherein said vaccine contains infectious bronchitis virus strain 1263 of the Massachusetts serotype.

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24. (Twice Amended) A method of vaccinating a poultry animal against infectious bronchitis (IB), which [consists essentially of] comprises obtaining a commercial vaccine against IB [which has not been approved or indicated for in ovo administration and thereafter reconstituting said vaccine] and administering said vaccine in ovo to a member selected from the group consisting of chickens, turkeys, ducks, geese, bantams, quail and pigeons, said member having maternal antibodies

to IB virus, wherein said [reconstituted] vaccine contains a live, avirulent strain of IB virus (IBV) in a quantity sufficient to confer immunity in an amount within the range of about  $10^{-1.0}$  EID<sub>50</sub> per dose to about  $10^{2.0}$  EID<sub>50</sub> per dose, and further wherein said method results in a percentage (%) protection in post-hatch member chicks surviving at 3 weeks of age of at least 89% against challenge from virulent IBV.

28. (Amended) The method of claim 24, wherein said [reconstituted] vaccine contains about  $10^{0.0}$  EID<sub>50</sub> per dose to about  $10^{2.0}$  EID<sub>50</sub> per dose.

29. (Amended) The method of claim 28, wherein said [reconstituted] vaccine contains about  $1.0^{0.0}$  EID<sub>50</sub> per dose to about [ $1.0^{2.0}$ ]  $1.0^{1.0}$  EID<sub>50</sub> per dose.

**NEW CLAIMS:**

30. The method of claim 24, wherein said vaccine is reconstituted prior to administration.

31. The method of claim 24, wherein said vaccine has not been approved or indicated for in ovo administration.

32. The method of claim 24, wherein said vaccine contains infectious bronchitis virus strain 1263 of the Massachusetts serotype.